SM.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,579	02/12/2002	Elaine M. Weidenhammer	267/173	1175

34263 7590 04/13/2004

O'MELVENY & MEYERS
114 PACIFICA, SUITE 100
IRVINE, CA 92618

EXAMINER	
CALAMITA, HEATHER	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 04/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/075,579	WEIDENHAMMER ET AL.	
	Examiner	Art Unit	
	Heather G. Calamita	1637	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02/12/2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *54-58 and 73-88* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *54-58 and 73-88* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02/12/2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: Page 12 of the heading should read, "Quantitative Shortened Amplicon Generation: Primer Extension and *in vitro* Transcription Techniques", as the paragraph refers to transcription not translation. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A) Claim 76 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 76 recites the limitation "method of claim 73" in line 1of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 54-58, 73-75, 78-80 are rejected under 35 U.S.C. 102(e) as being anticipated by Carrino et al. (USPN. 6,238,868, 5/29/2001).

Carrino et al. teach a method for electronically hybridizing a nucleic acid in a sample to a nucleic acid probe on an array and utilizing the hybridized nucleic acid as a template in a polymerase reaction, incorporating a labeled nucleotide into the nucleic acid that is amplified (see whole document, specifically col. 30 lines 30-60, col. 28 21-40). The label incorporated into the amplified nucleic acid is used for detection (see whole document, specifically col. 30 lines 30-60). They also teach the aforementioned method for use with a plurality of nucleic acids in a sample and a plurality of nucleic acid probes as well as at least one nucleic acid probe with the same sequence being located in two or more locations on the array (see whole document, specifically Fig 1A, col. 11 lines 34-44, and Fig 16).

Carrino et al. teach a nucleotide labeled with fluorescent, colorigenic, chemiluminescent and or affinity moieties (see whole document, specifically col. 16 lines 56-65, col. 17 lines 1-6 and 35-58).

Carrino et al. teach a polymerization reaction employing either DNA polymerase when utilizing DNA or a reverse transcriptase when utilizing RNA (see whole document, specifically col. 25 lines 50-67, col. 30 lines 30-61).

Carrino et al. further teach a method for electronically hybridizing a nucleic acid in a sample to a plurality of probes in a predetermined location on an array. Additionally, they teach multiple independent sample analysis on the same array by selectively and independently targeting different nucleic acids of interest from different samples to various microelectrode locations (see whole document, specifically col.10 lines 13-18, col.11 lines 34-41, col. 25 lines 1-5).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 76, 77, 87 and 88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carrino et al. (USPN. 6,238,868, 5/29/2001) in view of Little et al. (USPN 6,027,709, 02/22/2000).

Carrino et al. teach utilizing a hybridized nucleic acid as a template in a polymerase reaction, incorporating a labeled nucleotide into the nucleic acid that is amplified. The label incorporated into the amplified nucleic acid is used for detection (see whole document, specifically col. 30 lines 30-60). Additionally, Carrino et al. teach a nucleotide labeled with fluorescent, colorigenic, chemiluminescent and or affinity moieties (see whole document, specifically col. 16 lines 56-65, col. 17 lines 1-6 and 44-58).

Carrino et al. do not teach using a nucleotide labeled with a cyanine dye moieties.

Little et al teach a method of labeling nucleotides with cyanine dye moieties (see whole document, specifically col. 6 lines1-9, col. 5 12-17).

One of ordinary skill in the art at the time the invention was made would have been motivated to combine a method for utilizing a hybridized nucleic acid as a template in a polymerase reaction, incorporating a labeled nucleotide into the nucleic acid that is amplified, as taught by Carrino et al. with Little's method of labeling nucleotides with cyanine dye moieties to achieve the expected advantage of being able to detect and quantify the amplification product. It would have been prima facie obvious to apply Little's nucleotides labeled with a cyanine dye to Carrino's method of hybridization and amplification in order to both detect and quantify the amount of resulting target nucleic acid and evaluate the success of the amplification.

5. Claims 81 and 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carrino et al. (USPN. 6,238,868, 5/29/2001) in view of Lee et al. (USPN 6,207379, 03/27/2001).

Carrino et al. disclose a method for electronically hybridizing a nucleic acid in a sample to a nucleic acid probe on an array (see whole document, specifically col. 30 lines 30-60). Carrino et al. further teach utilizing the hybridized nucleic acid as a template in a polymerase reaction, incorporating a labeled nucleotide into the nucleic acid that is amplified. The label incorporated into the amplified nucleic acid is used for detection (see whole document, specifically col. 30 lines 30-60). Additionally, Carrino et al. teach a nucleotide labeled with fluorescent, colorigenic, chemiluminescent and or affinity moieties (see whole document, specifically col. 16 lines 56-65, col. 17 lines 1-6 and 44-58) and a polymerization reaction employing either DNA polymerase when utilizing DNA or a reverse transcriptase when utilizing RNA.

Carrino et al. do not teach the use of a control sequence probe.

Lee et al. teach including primers with sequences corresponding to a control housekeeping gene when amplifying target nucleic acid sequences as a means for evaluating proper nucleic acid amplification (see whole document, specifically col. 10 lines 6-36).

One of ordinary skill in the art at the time the invention was made would have been motivated to combine a method for utilizing a target nucleic acid electronically hybridized to an array as a template in a polymerase reaction, as taught by Carrino et al. with Lee's primers having sequences corresponding to a control housekeeping gene when amplifying target nucleic acids in order to achieve the expected advantage of being able to evaluate the quality/quantity of the amplification process.
Lee et al. states that utilizing an internal control to evaluate an amplification event would enable one to quantify the amount of resulting target nucleic acid as well as critically evaluate the success of the amplification (see whole document, specifically col. 10 lines 6-36). It would have been prima facie

obvious to apply Lee's primers to Carrino's method of hybridization and amplification in order to both quantify the amount of resulting target nucleic acid and evaluate the success of the amplification.

6. Claims 82-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carrino et al. (USPN. 6,238,868, 5/29/2001) in view of Fodor et al. (USPN 6,309,822 B1, 10/30/2001).

Carrino et al. disclose a method for electronically hybridizing a nucleic acid in a sample to a nucleic acid probe on an array (see whole document, specifically col. 30 lines 30-60).

Carrino et al. do not teach electronically hybridizing nucleic acids in a sample to nucleic acid probes at 5,10, 20, and 40 or more locations on the support where the sequence of at least one probe at each of the 5, 10, 20, 40 or more locations is different for the sequences of the probes at the other locations.

Fodor et al. teach a method for simultaneously detecting and or quantifiying the expression of a multiplicity of genes using a pool of target nucleic acids hybridized to an array of oligonucleotide probes immobilized on a surface, where the array comprises greater than 100 different oligonucleotides, each different nucleotide being localized in a predetermined region of the surface (see whole document, specifically col. 253-67, col. 3 lines 1-6).

One of ordinary skill in the art at the time the invention was made would have been motivated to combine a method for utilizing a target nucleic acid electronically hybridized to an array as a template in a polymerase reaction, as taught by Carrino et al. with Fodor's method for simultaneously detecting and/or quantifying the expression of a multiplicity of genes using a pool of target nucleic acids hybridized to an array of oligonucleotide probes immobilized on a surface, where the array comprises greater than 100 different oligonucleotides in order to achieve the expected advantage of being able to study a larger number of DNA's at a given time. It would have been prima facie obvious to apply Fodor's method for simultaneously detecting and or quantifying the expression of a multiplicity of genes to Carrino's method of hybridization and amplification in order to study large numbers of DNA's more efficiently.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather G. Calamita whose telephone number is 571.272.2876 and whose e-mail address is heather.calamita@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner can normally be reached on weekdays 7:30 A.M. - 4:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571.272.0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

hgc

Jeffrey Siew
JEFFREY SIEW
PRIMARY EXAMINER
4/7/04